APPENDIX F

Vaccine Safety

A Guide to Locating Information on Vaccine Safety
National Immunization Program
March 2002

This publication is presented for information purposes only, and no claims of accuracy are made. Mention of trade names, commercial products, or organizations does not constitute endorsement by the National Immunization Program (NIP) or the Centers for Disease Control and Prevention (CDC). This is not meant to be a comprehensive list of organizations and resources.

Introduction

This guide was produced by the National Immunization Program, part of the Centers for Disease Control and Prevention, to help individuals research issues surrounding vaccine safety. It contains information about government and international agencies and programs, as well as other organizations and selected resources.

This document is divided into four sections:

I. State, Local, and Federal Agencies and Programs

For general information on immunization, vaccine safety, clinics administering vaccines and school-entry requirements, contact your state or local health department.

State health departments on-line: www.cdc.gov/nip. Click on "partners."

Immunization grantees (National Immunization Program) and program managers -- see Appendix H, "Immunization Resources."

National Immunization Program (NIP)
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road, NE, MS E-05
Atlanta, GA 30333
Web site: www.cdc.gov/nip
National Immunization Information Hotline (Monday-Friday, 8:00am-11:00pm EST):
English: (800) 232-2522
Spanish: (800) 232-0233
E-mail: nipinfo@cdc.gov
The National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC) provides leadership for the planning, coordination, and implementation of immunization activities nationwide. The program helps monitor the safety and efficacy of vaccines by linking vaccine administration information with adverse event reporting and disease outbreak patterns. Through its toll-free telephone numbers and web site, NIP answers frequently asked questions about vaccines and vaccine safety, provides immunization schedules, and distributes vaccine-related publications.

Vaccine Adverse Event Reporting System (VAERS)
P.O. Box 1100
Rockville, MD 20849-1100
Information Line: (800) 822-7967 (24 hours)
Web site: www.vaers.org
VAERS is a national reporting system jointly administered the CDC and FDA to receive and analyze reports about adverse events that may be associated with vaccines. VAERS encourages the reporting of all clinically significant adverse events following any vaccine, whether or not the vaccine is believed to be the cause of the event. Health care providers, vaccine manufacturers, and consumers can report an adverse event 24 hours a day.

Clinical Immunization Safety Assessment (CISA) Network
National Immunization Program, CDC
Vaccine Safety and Development Branch
Epidemiology and Surveillance Division
1600 Clifton Road, NE
MS E-61
Atlanta, GA 30333
(404) 639-8256
Web site: CISA will have a link on the NIP web site in the near future, www.cdc.gov/nip
The Clinical Immunization Safety Assessment (CISA) Network was initiated in October 2001. Patients who have experienced adverse events following vaccination will be referred to a coordinated network of CISA academic centers to undergo enhanced clinical evaluation. The results of these evaluations will be used to gain a better understanding of the mechanisms underlying these events and to help develop protocols and guidelines for health care providers to help them manage similar situations. CISA centers will also serve as regional information sources to address clinical vaccine safety questions.

Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)
1401 Rockville Pike
HSM-40
Rockville, MD 20852
(800) 835-4709 (voice information system)
FAX: (888) CBER-FAX (fax information system)
Web site: www.fda.gov/cber
E-mail: octma@cber.fda.gov
The Center for Biologics and Evaluation Research (CBER) of the Food and Drug Administration (FDA) regulates biological products such as vaccines, blood products, tissue, and related drugs and devices. It maintains a consumer information hotline to answer questions on vaccine safety and regulations and distributes materials such as guidelines and informational letters to manufacturers. CBER's web site contains current vaccine information, including recalls and withdrawals of vaccine products.

Freedom of Information Staff (FOI)
Food and Drug Administration (FDA)
5600 Fishers Lane
HFI-35
Rockville, MD 20857
(301) 827-6567
FAX: (301) 443-1726
Web site: www.fda.gov/foi
Congress passed the National Childhood Vaccine Injury Act of 1986 to help ensure vaccine safety and availability, and to compensate people injured by vaccines. The legislation covers specific vaccines administered routinely during childhood, and ensures that consumers are entitled to information describing specific adverse events that may occur following receipt of these vaccines. Consumers can obtain this information from reports filed with the Vaccine Adverse Events Reporting System (VAERS). However, if more information on specific reports is desired, consumers can file a Freedom of Information Act (FOIA) request using the unique VAERS Report Identification Numbers.

National Vaccine Injury Compensation Program (VICP)
Health Resources and Services Administration (HRSA)
Parklawn Building, Room 8A-35
5600 Fishers Lane
Rockville, MD 20857
(800) 338-2382
FAX: (301) 443-8196
Web site: www.hrsa.gov/osp/vicp
The National Childhood Vaccine Injury Act of 1986 established the National Vaccine Injury Compensation Program (VICP) to compensate those who suffer certain vaccine-related injuries or death, while protecting doctors and manufacturers from lawsuits. Coordinated through the Health Resources and Services Administration (HRSA), the program office distributes an information package detailing criteria for eligibility, how to file a claim, and required documentation.

National Vaccine Program Office (NVPO)
4770 Buford Highway
MS K-77
Atlanta, GA 30341
(770) 488-2040
FAX: (770) 488-2064
Web site: www.cdc.gov/od/nvpo
E-mail: nvpo@cdc.gov
The National Vaccine Program Office (NVPO) was created in 1986 to coordinate and integrate immunization-related activities among all federal agencies, including the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, and the Health Resources and Services Administration. NVPO also develops and implements strategies designed to increase levels of immunization coverage and decrease levels of adverse reactions to vaccines.

II. International Organizations

Department of Vaccines and Biologicals
World Health Organization (WHO)
Avenue Appia 20
1211 Geneva 27
Switzerland
(+00 41 22) 791 21 11
FAX: (+00 41 22) 791 3111
Web site: www.who.int/vaccines
E-mail: vaccines@who.int
The World Health Organization was founded in 1948 by the United Nations to cooperate with national governments in the strengthening of health programs, technology, and information. The Department of Vaccines and Biologicals was established by WHO with the goal of protecting all people at risk against vaccine-preventable diseases. The program comprises five units: (1) Expanded Programme on Immunization, (2) Vaccine Development, (3) Quality Assurance and Safety of Biologicals, (4) Vaccine Assessment and Monitoring, and (5) Access to Technologies.

Division of Vaccines and Immunization (HVP)
Pan American Health Organization (PAHO)
525 23rd Street, NW
Washington, DC 20037
(202) 974-3000
FAX: (202) 974-3663
Web site: www.paho.org
E-mail: hvp@paho.org
Established in 1902, the Pan American Health Organization is the oldest continuously functioning international public health agency. The Division of Vaccines and Immunization (HVP) was established in 1999 and incorporates the former Special Program for Vaccines and Immunization. The division supports member states in the Region of the Americas by improving policies governing the adoption and delivery of vaccination programs, and by promoting the strengthening, development, and production of high-quality vaccines throughout the Region.

Global Alliance for Vaccines and Immunization (GAVI)
Lisa Jacobs
GAVI Secretariat
c/o UNICEF
Palais des Nations
1211 Geneva 10
Switzerland
41.22.909.50.19
FAX: 41.22.909.59.31
Web site: www.vaccinealliance.org
E-mail: Gavi@unicef.org
GAVI is a coalition of global leaders in immunization including UN organizations, national governments, foundations, NGO's, and the pharmaceutical industry, formed in response to stagnating global immunization rates and widening disparities in vaccine access among industrialized and developing countries.

III. Other Vaccine Safety-Related Organizations/Resources

American Academy of Pediatrics (AAP)
141 Northwest Point Boulevard
Elk Grove Village, IL 60007-1098
(847) 228-5005
FAX: (847) 228-5097
Web site: www.aap.org
E-mail: kidsdoc@aap.org
The American Academy of Pediatrics is an organization of 55,000 pediatricians dedicated to the health, safety and well-being of infants, children, adolescents, and young adults.

American Pharmaceutical Association (APhA)
2215 Constitution Avenue, NW
Washington, DC 20037-2985
(202) 628-4410
FAX: (202) 783-2351
Web site: www.aphanet.org
The American Pharmaceutical Association is an organization of over 50,000 pharmacists and allied health professionals involved in ongoing efforts to improve public health by educating its members and the public about the pharmaceutical profession and its products, including vaccines.

Immunization Action Coalition (IAC)
1573 Selby Avenue
Suite 234
Saint Paul, MN 55104
(651) 647-9009
FAX: (651) 647-9131
Web site: www.immunize.org
E-mail: admin@immunize.org
The Immunization Action Coalition (IAC) is a nonprofit organization that promotes physician, community, and family awareness of, and responsibility for, appropriate immunization of people of all ages against vaccine-preventable diseases. The Hepatitis B Coalition is a program of IAC that promotes hepatitis B vaccination for all infants, children, and adolescents; hepatitis B screening for all pregnant women; testing and vaccination for high-risk groups; and education and treatment for hepatitis B carriers. Semi-annual newsletters containing valuable resources and news are available for both programs.

The Immunization Gateway: Your Vaccine Fact-Finder
Web site: www.immunofacts.com
This site is an online vaccine/immunization fact-finder that links to many of the latest resources on vaccines. It is produced by Facts and Comparisons, a commercial publisher of drug-related information.

Infectious Diseases Society of America (IDSA)
66 Canal Center Plaza
Suite 600
Alexandria, VA 22314
877-341-6644
FAX: (703) 299-0204
Web site: www.idsociety.org
E-mail: info@idsociety.org
The Infectious Diseases Society of America seeks to provide comprehensive information on infectious disease prevention to health care providers and the general public. IDSA sponsors the Vaccine Initiative, which communicates the benefits of routine immunization.

Institute for Vaccine Safety
The Johns Hopkins University
Bloomberg School of Public Health
615 North Wolfe Street
Suite W5515
Baltimore, MD 21207
(410) 955-2955
FAX: (410) 502-6733
Web site: www.vaccinesafety.edu
E-mail: info@vaccinesafety.edu
Established in 1997, the purpose of the Institute for Vaccine Safety is to obtain and distribute objective information on vaccines and vaccine safety to physicians, the general public, decision makers, and the media. It also investigates vaccine safety questions when data are inconclusive and conducts vaccine safety evaluations following vaccine licensure.

National Network for Immunization Information (NNii)
Infectious Diseases Society of America
66 Canal Center Plaza
Suite 600
Alexandria, VA 22314
(877) 341-6644
FAX: (703) 299-0204
Web site: www.immunizationinfo.org
E-mail: nnii@idsociety.org
The National Network for Immunization Information (NNii) provides up-to-date, science-based information about immunization to the public, health professionals, policy makers, and the media to help them understand the issues involved and make informed decisions. NNii is a partnership of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society of America, the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, the American Nurses Association, and the National Association of Pediatric Nurse Practitioners.

National Partnership for Immunization (NPI)
Web site: www.partnersforimmunization.org
A joint program of the National Foundation for Infectious Diseases and the National Healthy Mothers, Healthy Babies Coalition, the National Partnership for Immunization (NPI) seeks to increase national awareness of the importance and acceptance of immunization across the life span through outreach partnerships with public and private organizations. NPI develops educational initiatives and issues reports designed to improve immunization knowledge. NPI recently published a Reference Guide on Vaccines and Vaccine Safety.

Parents of Kids with Infectious Diseases (PKIDS)
P.O. Box 5666
Vancouver, WA 98668
(877) 55-PKIDS
FAX: (360) 695-6941
Web site: www.pkids.org
E-mail: pkids@pkids.org
The goal of Parents of Kids with Infectious Diseases (PKIDS) is to educate the public about infectious diseases, their prevention and transmission, and current medical advances. PKIDS also provides emotional, informational, and financial support to families of affected children and works to reduce the societal stigma associated with those who have infectious diseases.

The Vaccine Education Center at The Children's Hospital of Philadelphia
215-590-9990
Web site: www.vaccine.chop.edu
The Vaccine Education Center at The Children's Hospital of Philadelphia provides current information to parents and health care professionals about how vaccines work and are manufactured, whether vaccines are still necessary, their recommendation process, whether vaccines are safe, and their recommended schedules. The center also provides informational and audiovisual materials and speakers programs.

IV. Selected Vaccine Safety-Related Publications and Products

A. Government Publications

Advisory Committee on Immunization Practices (ACIP) Recommedations
Advisory Committee on Immunization Practices (ACIP)
Division of Epidemiology and Surveillance
National Immunization Program
1600 Clifton Road, NE
MS E-61
Atlanta, GA 30333
(404) 639-8096
FAX: (404) 639-8520
Web site: www.cdc.gov/nip/acip. Click on "recommendations."
E-mail: acip@cdc.gov
The Advisory Committee on Immunization Practices (ACIP) is a committee composed of 15 experts in fields associated with immunization who provide recommendations designed to reduce the incidence of vaccine-preventable diseases and increase the safe usage of vaccines.
ACIP recommendations printed in Morbidity and Mortality Weekly Report (MMWR) can be accessed on-line through the National Immunization Program web site's sub-site for ACIP. In addition, the ACIP sub-site page for "recommendations" has a link to other recent articles about immunization that have been printed in MMWR.

Guide to Contraindications to Childhood Vaccinations
This booklet contains information on contraindication to recommended childhood vaccines. It was developed using information derived from the Standards for Pediatric Immunization Practices, recommendations of the Advisory Committee on Immunization Practices (ACIP), and those of the Committee on Infectious Diseases (Red Book Committee) of the American Academy of Pediatrics (AAP). This publication can be obtained on the NIP web site at www.cdc.gov/nip.

Parents Guide to Childhood Immunization (2001)
This newly revised 94-page booklet, available in English and Spanish, introduces parents to 12 childhood diseases and the vaccines that can prevent them, vaccine safety issues, a glossary of immunization terms, and the current childhood vaccination schedule. This publication can be obtained from the NIP web site at www.cdc.gov/nip.

Six Common Misconceptions About Vaccination and How to Respond to Them (1996)
This booklet discusses six misconceptions about vaccination often cited by parents as reasons they question the need to have their children immunized. Each misconception is refuted based on scientific information and research findings. The misconceptions include the concepts of community immunity, whether there are vaccine "hot lots," vaccine side effects, and whether diseases still exist. This publication can be viewed on the NIP web site at www.cdc.gov/nip.

Vaccine Information Statements
The National Childhood Vaccine Injury Act requires that vaccine information materials be developed for each vaccine covered by the Act. These materials, known as *Vaccine Information Statements*, must be provided by all public and private vaccination providers each time a vaccine is administered. Copies of Vaccine Information Statements are available from state health authorities responsible for immunization, or they can be obtained from CDC's National Immunization Program website at http://www.cdc.gov/nip. Translations of Vaccine Information Statements into languages other than English are available from certain state immunization programs and from the Immunization Action Coalition website at http://www.immunize.org.

Task Force on Safer Childhood Vaccines: Final Report and Recommendations (1998)
National Institute on Allergy and Infectious Diseases (NIAID), NIH
Office of Communications and Public Liaison
Building 31, Room 7A-50
31 Center Drive
MSC 2520
Bethesda, MD 20892-2520
Web site: www.niaid.nih.gov/
A summary of the findings and recommendations of the Task Force on Safer Childhood Vaccines concerning improvements in research, manufacturing, licensing, distribution, administration, testing, and vaccine safety monitoring of childhood vaccines.

Vaccine Safety: What Parents Need to Know (pamphlet)
Michigan Department of Community Health
Information & Education Coordinator
Division of Immunization
4641 Willoughby Road
Holt, MI 48842
1-888-76-SHOTS
Web site: www.hpclearinghouse.org

What If You Don't Immunize Your Child (pamphlet)
California Department of Health Services
Immunization Branch
2151 Berkeley Way
Room 712
Berkeley, CA 94704
(510) 540-2381
FAX: (510) 540-2650
Web site: www.dhs.ca.gov

Plain Talk About Childhood Immunizations (booklet)
This booklet is produced by both the State of Alaska and Seattle, Washington departments of health and is tailored to meet each region's immunization issues.
State of Alaska
Department of Health and Social Services
Section of Epidemiology
Immunization Program
3601 C Street
Suite 540
Anchorage, AK 99503
(907) 269-8000
FAX: (907) 561-0847
Web site: www.epi.hss.state.ak.us/programs/infect/immune.html

Department of Public Health – Seattle & King County
999 Third Avenue
Suite 900
Seattle, WA 98104
(206) 296-4774
FAX: (206) 296-4803
Web site: www.metrokc.gov/health

B. Institute of Medicine (IOM) Reports and Publications

National Academy Press
2101 Constitution Avenue, NW
P.O. Box 285
Washington, DC 20055
(888) 624-8373
FAX: (202) 334-2451
Web site: www.nap.edu

The Institute of Medicine (IOM) was established in 1970 by the National Academy of Sciences. IOM provides objective, timely, authoritative information and advice about health and science policy to government, the private sector, health professions, and the public. IOM established an Immunization Safety Review Committee in 2001 at the request of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) to review existing and emerging immunization safety concerns during the time period 2001-2003.

The reports and publications listed below related to vaccine safety that have been issued by both IOM and its Immunization Safety Review Committee can all be read on-line for free through the web site of the National Academy Press (NAP). Some reports can also be ordered in print form, depending on how recently they were published.

- Immunization Safety Review: Multiple Immunizations and Immune Dysfunction (2002)
- Immunization Safety Review: Thimerosal-Containing Vaccines and Neurodevelopmental Disorders (2001)
- Immunization Safety Review: Measles-Mumps-Rubella Vaccine and Autism (2001)
- CDC Anthrax Vaccine Safety and Efficacy Research Program: Interim Report (2001)
- The Anthrax Vaccine: Is It Safe? Does It Work? (2002)
- An Assessment of the Safety of the Anthrax Vaccine: A Letter Report (2000)
- Vaccine Safety Forum: Summaries of Two Workshops (1997)
- Risk Communication and Vaccination: Workshop Summary (1997)
- Research Strategies for Assessing Adverse Events Associated with Vaccines: A Workshop Summary (1994)
- Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality (1993)
- Adverse Effects of Pertussis and Rubella Vaccines (1991)

C. Books and Videos

Immunofacts
Facts and Comparisons, Inc.
St. Louis, MO
(800) 223-0554
FAX: (314) 878-5563
Web site: www.drugfacts.com
This looseleaf-style book contains technical information and a glossary of terms that are updated monthly about indications, product availability, dosage, and safety limits for immunological drugs and vaccines.

Vaccines, 3rd edition (1999)
"Safety of Vaccines" chapter, by Robert T. Chen, M.D.
Authors: Stanley A. Plotkin, M.D., and Walter A. Orenstein, M.D., editors
Elsevier Health Science, Inc.
St. Louis, MO
(800) 545-2522
Web site: www.wbsaunders.com
A comprehensive reference book that describes all vaccines currently in use in addition to those about to be licensed, along with many other issues concerning immunization. Of particular interest are chapters covering vaccine safety, vaccine regulation and testing, immunization law, combined vaccines, and immunizing the immunocompromised.

Vaccines: What Every Parent Should Know (revised edition, 1999)
Authors: Paul A. Offit, M.D., and Louis M. Bell, M.D.
Hungry Minds Publishing, Inc.
New York, NY
(800) 434-3422
Web site: www.hungryminds.com
This book contains information about vaccines routinely administered to children and the diseases they prevent, whether vaccines are still necessary; how vaccines work; when to withhold or delay vaccination; vaccine manufacturing, testing, and recommendation processes; multiple and combination vaccinations; and vaccine safety issues.

Vaccinating Your Child: Questions and Answers for the Concerned Parent (2000)
Authors: Sharon G. Humiston, M.D., and Cynthia Good
Peachtree Publishers, Ltd.
Atlanta, GA
(404) 876-8761
Web site: www.peachtree-online.com
This book contains information about vaccines routinely administered to children and thediseases they prevent, whether vaccines are still necessary; how vaccines work; when to withhold or delay vaccination; vaccine manufacturing, testing, and recommendation processes; multiple and combination vaccinations; and vaccine safety issues.

Vaccines: Separating Fact from Fear
Vaccine Education Center at The Children's Hospital of Philadelphia
215-590-9990
Web site: www.vaccine.chop.edu
This 27 minute videotape was created to provide comprehensive, easy to understand answers to parent's questions about the need for and safety of vaccines.

Immunization Techniques: Safe, Effective, Caring
California Department of Health Services' Immunization Branch
(916) 657-2861
This 35 minute video, produced by the California Department of Health Services' Immunization Branch, includes the latest information on injection techniques for immunizaing children and adults. The video can be ordered from the Immunization Action Coalition web site at www.immunize.org.

National Childhood Vaccine Injury Act

Vaccine Injury Table

Effective August 26, 2002

Vaccine	Adverse Event	Time Interval
I. Tetanus toxoid-containing vaccines (e.g., DTaP, DTP-Hib, DT; Td, or TT)	A. Anaphylaxis or anaphylactic shock [1]	0-4 hours
	B. Brachial neuritis[6]	2-28 days
	C. Any acute complication or sequela (including death) of above events[4]	Not applicable
II. Pertussis antigen-containing vaccines (e.g., DTaP, DTP, DTP-Hib)	A. Anaphylaxis or anaphylactic shock [1]	0-4 hours
	B. Encephalopathy (or encephalitis)[2]	0-72 hours
	C. Any acute complication or sequela (including death) of above events[4]	Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock [1]	0-4 hours
	B. Encephalopathy (or encephalitis)[2]	5-15 days
	C. Any acute complication or sequela (including death) of above events[4]	Not applicable
IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)	A. Chronic arthritis[5]	7-42 days
	B. Any acute complication or sequela (including death) of above event[4]	Not applicable
V. Measles virus-containing vaccines (e.g., MMR, MR, M)	A. Thrombocytopenic purpura[7]	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient[8]	0-6 months
	C. Any acute complication or sequela (including death) of above events[4]	Not applicable
VI. Polio live-virus-containing vaccines (OPV)	A. Paralytic polio - in a non-immunodeficient recipient - in an immunodeficient recipient - in a vaccine-associated community case	 0-30 days 0-6 months Not applicable
	B. Vaccine-strain polio viral infection[9] - in a non-immunodeficient recipient - in an immunodeficient recipient - in a vaccine-associated community case	 0-30 days 0-6 months Not applicable
	C. Any acute complication or sequela (including death) of above events[4]	Not applicable
VII. Polio inactivated-virus containing vaccines (e.g., IPV)	A. Anaphylaxis or anaphylactic shock[1]	0-4 hours
	B. Any acute complication or sequela (including death) of above event[4]	Not applicable

Vaccine	Adverse Event	Time Interval
VIII. Hepatitis B antigen-containing vaccines	A. Anaphylaxis or anaphylactic shock[1]	0-4 hours
	B. Any acute complication or sequela (including death) of above event[4]	Not applicable
IX. Haemophilus influenzae type b polysaccharide conjugate vaccines	A. No condition specified for compensation	Not applicable
X. Varicella vaccine	A. No condition specified for compensation	Not applicable
XI. Rotavirus vaccine	A. No condition specified for compensation	Not applicable
XII. Vaccines containing live, oral, rhesus-based rotavirus	A. intussusception	0-30 days
	B. Any acute complication or sequela (including death) of above event[4]	Not applicable
XIII. Pneumococcal conjugate vaccines	A. No condition specified for compensation	Not applicable
XIV. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by Secretary, HHS of a notice of coverage.	A. No condition specified for compensation	Not applicable

Qualifications and Aids to Interpretation

(1) Anaphylaxis and anaphylactic shock mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, edema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) Encephalopathy. For purposes of the Vaccine Injury Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" (see "D" below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:

(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;

(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and

(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):

(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) Chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurologic state after the acute encephalopathy shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed under section 2111(b) of the Act for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record.

(3) Seizure and convulsion. For purposes of paragraphs (b)(2) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(4) Sequela. The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(5) Chronic Arthritis. For purposes of the Vaccine Injury Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination;

(C) Medical documentation of an antibody response to the rubella virus.

For purposes of the Vaccine Injury Table, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

(6) Brachial neuritis is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(7) Thrombocytopenic purpura is defined by a serum platelet count less than 50,000/mm^3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections,

toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) Vaccine-strain measles viral infection is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(9)Vaccine-strain polio viral infection is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

For additional information call our public information line at 1-800-338-2382.

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

VAERS

For CDC/FDA Use Only
VAERS Number _____
Date Received _____

Patient Name:
Last First M.I.
Address
City State Zip
Telephone no. (____) _____

Vaccine administered by (Name):
Responsible Physician _____
Facility Name/Address
City State Zip
Telephone no. (____) _____

Form completed by (Name):
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)*
City State Zip
Telephone no. (____) _____

1. State | 2. County where administered | 3. Date of birth mm dd yy | 4. Patient age | 5. Sex ☐ M ☐ F | 6. Date form completed mm dd yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm dd yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm dd yy Time _____ AM PM

11. Adverse event onset mm dd yy Time _____ AM PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medial conditions(specify)

20. Have you reported this adverse event previously? ☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under
22. Birth weight _____ lb. _____ oz.
23. No. of brother and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/Immunization project
24. Mfr./imm. proj. report no.
25. Date received by mfr./imm.proj.
26. 15 day report? ☐ Yes ☐ No
27. Report type ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1(FDA)

F

"Fold in thirds, tape & mail - DO NOT STAPLE FORM"

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE

VAERS
P.O. Box 1100
Rockville MD 20849-1100

DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed)

GENERAL

Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine orthat person's legal representativewill not be made available tothe public, but may be available to the vaccinee or legal representative.
Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms diagnosis, treatment and recovery should be noted.
Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
Item 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
Item 13: List ONLY those vaccines given on the day listed in Item 10.
Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one priorvaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
Item 26: This space is for manufacturers' use only.